GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1565
ANSWERED ON:04.03.2016
Unethical Practices in Clinical Trials
Meena Shri Harish Chandra

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government is aware that the pharmaceutical research companies are resorting to unethical practices in conducting clinical trials and keeping the volunteers in dark about side effects, if so, the details thereof;

(b) whether such practices/irregularities are affecting poor people especially those belonging to SCs/STs, if so, the details thereof;

(c) whether the Ethics Committee under the Drugs and Cosmetics Act has failed to check such violations by such companies; and

(d) if so, the action taken by the Government against such pharmaceutical research companies?

Answer

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)
(a) to (d): It has been reported in some cases that the requirements of Schedule Y to the Drugs and Cosmetics Rules, 1945 and ethical guidelines are not being followed scrupulously. The Central Drugs Standard Control Organisation (CDSCO) has carried out the inspection of various clinical trial sites and/or Ethics Committees and based on inspection findings, action is initiated as per provisions of the Drugs and Cosmetics Rules, 1945.